REMARKS

Claim 9 defines a surgically implantable biarticular disk designed to replace a CMC or TMT joint which would not be anticipated by the disclosure of U.S. Published Application No. 2003/0093152 to Pedersen et al (hereinafter Pedersen). Applicant's claimed biarticular disk is designed to replace a CMC or TMT joint. It provides a pair of solid surfaces, and when implanted in space created by resecting the articular surfaces of both bones, each bone of the joint slides on the respective, mating, convex, articular surface of the disk.

The Examiner states that Pedersen explicitly teaches that the device is adapted in its structure to provide "sliding/rotating movement"; however, scrutiny of paragraph 24 of Pedersen will show that the sliding/rotating movement is via "internal movement of at least a part of the device". This is more particularly pointed out in paragraph 149, where it is stated that the surfaces of the device in contact with the biological surfaces will be subject to frictional resistance and the sliding/rotating movement takes place by internal movement, i.e. movement within the flexible device. This function is perhaps best illustrated by Figures 2 where it can be seen that there is missing cartilage in the region between the head surface of the femur and the acetabulum; in Figure 3, the device 11 has been inserted into this gap where it deforms to lie in juxtaposition with both surfaces. Its flexible form serves as a cushion between the two articular surfaces where it is squeezed and conforms to the boundaries of the region separating the two surfaces. Thereafter, when the head of the femur moves relative to the socket, the device internally stretches. Accordingly, the device is made from material chosen for its resilient properties. It is pointed out in paragraph 150 that the material should be elastic in order to allow deformation of its shape without damage to the surface. In the exemplary method described in

paragraphs 173-175, the prosthetic device is initially deformed as by the use of forceps in order to insert the device into the space at the particular joint. As pointed out in paragraph 179, the device serves a spacer function and a capability to allow sliding/rotating movement of the joint by internal movement of the device, which constitutes a resilient member (see paragraph 179).

Further, with respect to the Examiner's specific reading of Pedersen on claim 9, Pedersen does not have a pair of "convex spherical articular surfaces 49" in Figure 14. The surfaces are clearly frustoconical; note the two straight line boundaries of the cross section of the triangular segment 50. Even more relevant is the fact that the Pedersen disk does not have a modulus of elasticity similar to cortical bone. The Examiner's reference to claim 50 correctly reports that the Pedersen device might have a modulus of elasticity of 10 MPa-50 MPa. In contrast, cortical bone has a modulus of elasticity between about 15-25 GPa-see, for example, U.S. Patent No. 6,090,145, lines 58-67. These values correspond favorably with test data published by Rho et al in *Biomaterials 18* (1997) 1325-30, "Elastic Properties of Human Cortical and Trabecular Lamellar Bone Measured By Nanoindentation", copy attached as Exhibit A. At page 1328, test results are reported of cortical bone having a Young's modulus between about 20.5 and 26.6 GPa.

One GPa (Giga Pascal) equals 1,000 MPa. Accordingly, the modulus of elasticity of cortical bone is about 1,000 times that of the resilient material chosen by Pedersen.

It is submitted that claim 37 of Pedersen artfully describes the function of the Pedersen device, namely, one that is capable of replacing or supplementing worn or damaged cartilage in the joint and capable of preventing further wear of native cartilage. In short, Pedersen discloses a soft, resilient, cushioning device that can be deformed to fill the gap between two articular

bone surfaces in a joint where the cartilage has become worn or damaged; the Pedersen implant is not a biarticular disk that is designed to replace such a joint. As pointed out in the abstract of Pedersen, it is directed to a device that can be deformed to allow its insertion into a joint cavity between bones of a human joint. Applicant's device replaces the articular surfaces of the joint with two new pairs of spherical, sliding articular surfaces; the two spherical disk surfaces mate with the newly created surfaces in, for example, the metacarpus and the trapezium as illustrated in Figures 4-7 of Applicant's drawings.

Accordingly, it is submitted that the rejection of claim 9 as anticipated under 35 USC 102 by Pedersen should be reconsidered and withdrawn, and claim 9 along with dependent claims 10-15 should be allowed over the disclosure of Pedersen.

Claim 1 would not be obvious in view of the disclosure of Pedersen and further in view of the disclosure of U.S. Patent No. 4,055,862 to Farling (hereinafter Farling). As explained just above, Pedersen discloses an elastic annular cushion for filling a gap in a joint between two articular bone surfaces where cartilage has been worn or destroyed; the Pedersen device is not an integral, solid nonflexible disk that is used to replace a CMC joint. As now specifically recited in amended claim 1, the disc is designed for implantation of into space created by resecting the base of the metacarpus and the distal surface of the trapezium to provide two convex solid articular spherical surfaces; this allows the disk, which is a graphite core coated with wear-resistant pyrocarbon, to mate with and slide against the two resected concave spherical surfaces.

Farling teaches, in Figure 6, the construction of a prosthesis having an upper surface 72 that will coact with a metallic femoral condyle 82 to allow sliding movement therebetween. The Farling prosthesis 60 is made of ultrahigh molecular weight polyethylene resin filled with

graphite fibers or the like. The teaching is use of a filled, high-molecular weight polymer which is filled with fibers because graphitic carbon particles or flakes were deemed unsuitable. However, the device is primarily a polymeric material. The reference to which the Examiner called attention, column 4, line 54, is merely one directed to the manufacture of the graphite fibers, i.e. threads of epoxy, phenolic or other polymeric resin are incinerated, i.e. pyrolyzed in an oxygen-free atmosphere to create the crystalline graphite fibers. On reflection, it is believed that the Examiner will see that Farling would add nothing of relevance to Pedersen. There is no reason why one would wish to attempt to substitute this fiber-filled dense polymeric material for the soft, resilient cushion material of Pedersen; such would totally destroy the purpose of Pedersen, which is namely to allow deformation of the device by forceps or the like to permit its insertion into a gap between bones (to fill that gap as shown in Figure 3) as a cartilage replacement.

Accordingly, reconsideration of the rejection of claim 1 on the basis of the disclosure of Pedersen in view of the disclosure of Farling should be reconsidered and withdrawn, and claim 1 and dependent claims 2-8 should be allowed.

With respect to the rejection of claims 7 and 8 further in view of U.S. Patent No. 5,743,918 to Calandruccio et al (hereinafter Calandruccio) and the *Journal of Hand Surgery* article to Trumble et al (hereinafter Trumble et al), it is correct that Calandruccio and Trumble teach the resection of facing surfaces of, for example, the first metacarpal bone and the trapezium and the replacement of the joint by a prosthesis. It is in fact procedures such as those taught in Calandruccio and Trumble upon which Applicant's invention improves. As opposed to, for example, a solid spherical ball, Applicant's biarticular disk provides a pair of oppositely

facing convex hard spherical surfaces which surround an internal flaring passageway through which a flexible restraining cord, such as a harvested tendon, can be threaded; Applicants' biarticular disk has been found to constitute a superior solution to the reconstruction of a CMC joint or the like in comparison to such a ball or the like.

As pointed out above, the soft, resilient cushion of Pedersen having a modulus of elasticity 1,000 times less than that of bone would be clearly unsuitable for such a reconstruction. Pedersen strives to preserve the joint between two articulating bones by inserting a cartilage replacement, whereas Applicant's invention is directed to the reconstruction of the joint, which is accompanied by resection of the two bones in question. Accordingly, it is submitted that claims 1-8 define invention which is an improvement over the prior art and deserving of patent protection.

Claim 16 (as well as claim 15) would not be obvious over the disclosure of Pedersen in view of Calandruccio and Trumble. Claim 15 is dependent upon claim 9 and should be allowable for that reason. Claim 16 defines the sequence of steps which includes resecting the base of the metacarpus and the distal surface of the trapezium to provide concave articular surfaces of similar spherical curvature and creating passageways that open into such resected concave surfaces, providing a circular disk with a pair of convex spherical articular surfaces of the same spherical curvature as said resected articular surfaces, which convex surfaces are interconnected at their peripheries by a curved rim surface that is a segment of a spheroid and transition to a central flaring hole. This specifically shaped disk is then surgically implanted into the resected region between the metacarpus and the trapezium so that each respective bone spherical concave surface slides on the respective convex solid, nonflexible spherical articular

surface of the disk and so that a flexible restraining cord can be routed through such central flaring hole. For the reasons set forth above, it is the employment of the biarticular disk of this unique shape to reconstruct the CMC joint in this manner that distinguishes and improves upon these two prior art references. Accordingly, it is requested that the rejection on the basis on these three references be reconsidered and withdrawn and claims 16-20 be allowed.

In view of the foregoing amendments and remarks and in the absence of more pertinent prior art, it is believed that independent claims 1, 9 and 16 and dependent claims 2-8, 10-15 and 17-20 should be allowed. It is believed that this application has been placed in condition for allowance, and favorable action is courteously solicited.

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Respectfully submitted,

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